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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,076	09/02/2005	Adelbert Bacher	13555-00001-US	7148
23416 7590 09/17/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER SHEN, BIN	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 09/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/543,076

Applicant(s)

BACHER ET AL.

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The IDS received 7/21/2005, the preliminary amendment received 7/21/2005, 10/13/2005 have been entered.

Claims 1-11 are presented for examination on the merits.

Specification

1. Brief description of drawing is missing in specification.
2. The abstract of the disclosure is objected to because the abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b). A new abstract on a separate page is required to replace the current abstract, which is the first page of the WO document of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 refer to a sample without giving a true technical characterization. Moreover, no such specific sample is defined

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in the specification. The closest potential support for the claimed subject matter is on page 6, lines 11-22 of the descriptive portion of the specification, where it gives examples of where the sample comes from. However, this does not actually provide support for the claim, no structural characteristics of such sample is provided, nor is there any indication that the applicant had possession of the claimed sample. One skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claims fails to comply with the written description requirement. Further, since this Examiner cannot determine what sample is claimed, it cannot be searched.

4. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to disclose any particular structural components for the claimed sample. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to prepare the claimed sample. Furthermore, an assay for testing a sample is not equivalent to a positive recitation of how to make a sample/product. The claims fail to meet the enablement requirement for the "how to make" prong of 35 U.S.C. 112, first paragraph. Thus, the skilled artisan would not been able to make and use the sample as claimed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11 "capable of" does not state what actually occurs.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adam et al. (Proc. Nat. Aca. Sci. 2002;99(19):12108-12113).

Adam et al. teach an assay of enzyme activity that converts 1-hydroxy-2-methyl-2-(E)-butenyl 4-diphosphate into isopentenyl diphosphate and/or dimethylallyl diphosphate comprising the following steps: a) reacting an aqueous mixture containing 1-

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hydroxy-2-methyl-2-(E)-butenyl 4-diphosphate, a 1-hydroxy-2-methyl-2-(E)-butenyl 4-diphosphate reductase, and a reducing agent (NADH, FAD including flavodoxin and a flavodoxin reductase) under predetermined reaction conditions (such as at 37°C for 1 hr-see page 12109, 4th full paragraph, line 8 read as under aerobic conditions) for a predetermined period of time (page 12109, from the end of left column to the top paragraph of the right column); b) analyzing the reaction mixture obtained in step a) for the produced amount of dimethylallyl diphosphate (page 12109, right column, 1st full paragraph). The reaction is stopped by addition of trichloroacetic acid (page 12109, right column, lines 4-5), NADPH is used as NAD(P)H (page 12111, right column, 1st full paragraph, lines 6-7), and the 1-hydroxy-2-methyl-2-(E)-butenyl 4-diphosphate reductase is IspH (abstract). Adam also teaches that the enzymes of the pathway are potential target for antiinfective drugs and the assay can be used for drug screening (page 12108, end of the left column and top of the right column).

Adam does not teach to test a sample for the presence or absence of inhibition of the enzymatic activity, the consumed amount of NAD(P)H, produced amount of NAD(P)⁺ are measured photometrically, the reaction is carried out under anaerobic conditions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay of Adam et al. to test a sample for the presence or absence of inhibition of the enzymatic activity because Adam teaches that the enzymes of the pathway are potential target for antiinfective drugs and the assay can be used for drug screening (page 12108, end of the left column and top of the right

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column). One would have been motivated to make the modification because Adam et al. specifically described that the agent has been shown to inhibit the enzymatic pathway can protect mice from infection (page 12108, left column, 3rd paragraph, lines 3-5), and would reasonably have expected success in view of Adam's teaching. The adjustment of particular conventional working conditions (e.g., under anaerobic conditions, use of photometrical method instead of measuring radioactivity as taught by Adam to measure NAD(P)H/NAD(P)⁺) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

7. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday

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through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.



MICHAEL MELLER
PRIMARY EXAMINER

B Shen

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